DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 3, 2014

Asahi Intecc Co., Ltd.
% Candace Cederman
Senior Regulatory Affairs Consultant
CardoMed Device Consultants, LLC
5523 Research Park Drive, Suite 205
Baltimore, Maryland 21228

Re: K141339
Trade/Device Name: ASAHI PTCA Guidewire System, ASAHI RG3
Regulation Number: 21 CFR 870.1330
Regulation Name: Guidewire System
Regulatory Class: Class II
Product Code: DQX
Dated: September 25, 2014
Received: September 26, 2014

Dear Candace Cederman:

This letter corrects our substantially equivalent letter of September 25, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ASAHI PTCA Guidewire ASAHI RG3

Indications for Use:

ASAHI PTCA Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The ASAHI PTCA Guide wires are not to be used in the neurovasculature.

Prescription Use ___**X**____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary
[as required by 21 CFR 807.92(c)]

ASAHI PTCA Guide Wire ASAHI RG3

510(k) K141339

APPLICANT	Asahi Intecc Co., Ltd. 1703 Wakita-cho, Moriyama-ku Nagoya, Aichi 463-0024 Japan
OFFICIAL CORRESPONDENT	Yoshi Terai President, CEO Asahi Intecc USA, Inc. 2500 Red Hill Avenue, Suite 210 Santa Ana, CA 92705 Tel: (949) 756-8252 FAX: (949) 756-8165 e-mail: asahi.ra-fda@asahi-intecc.com
TRADE NAME:	ASAHI PTCA Guidewire System, ASAHI RG3
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1330
CLASSIFICATION NAME:	Catheter, Guide, Wire
PRODUCT CODE	DQX- Catheter Guide Wire
PREDICATE DEVICES:	K031277, Asahi Prowater Guidewire, Asahi Grand Slam K133865, ASAHI PTCA Guide Wire ASAHI Gaia
DATE PREPARED:	May 16th, 2014

INTENDED USE:

ASAHI PTCA Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The ASAHI PTCA Guide Wires are not to be used in the neurovasculature.

DESCRIPTION:

The product, ASAHI PTCA Guide Wire ASAHI RG3 (hereinafter ASAHI RG3 and ASAHI RG3 Soft), is intended to facilitate the insertion of an inflatable balloon catheter and other devices for treating narrowing and obstruction of the blood vessels.

The basic structure of the ASAHI RG3 and ASAHI RG3 Soft consists of a taper core wire and a coil. The taper core wire and the coil are soldered. The coil is radiopaque in part length so its position can be easily confirmed under radioscopy. In addition to this, coatings are applied on the surface of the product. The distal end of ASAHI RG3 and ASAHI RG3 Soft are coated with hydrophilic polymer. On the other hand, the proximal end of the taper core of ASAHI RG3 and ASAHI RG3 Soft wire is coated with silicone oil.

COMPARISON TABLE WITH PREDICATE DEVICES:

Comparisons of the ASAHI PTCA Guide Wire ASAHI RG3 and predicate devices show that the technological characteristics of the ASAHI RG3 such as the intended use, components, design, materials, sterilization method, shelf life and operating principle are similar to the currently marketed predicate devices. The ASAHI PTCA Guide Wire ASAHI RG3 has an overall length of 330 cm and a nominal outer diameter of 0.26 mm.

NON CLINICAL TESTING / PERFORMANCE DATA:

Non clinical laboratory testing was performed on the ASAHI RG3 to determine substantial equivalence. The following testing/assessments were performed:

- Tensile Strength
- Torque Strength
- Torqueablity
- Tip Flexibility
- Coating Adhesion/Integrity
- Catheter Compatibility

BIOCOMPATIBILITY:

The ASAHI RG3 Guidewire was compared to the predicate devices. Based on similariites of the materials used in the subject devcie to its predicates, the biocompatibiity of the ASAHI RG3 was verified to be the same as those of the predicates.

CONCLUSION:

The ASAHI RG3 GuideWire has the same intended use and similar technological characteristics such as components, design, materials, sterilization method, shelf life and operating principles as the predicate devices. Performance data demonstrates that the device functions as intended, and is as safe and effective as the predicate devices.

Therefore, the ASAHI PTCA Guide Wire ASAHI RG3 is substantially equivalent to the predicate devices.